July 2014 HHS Retrospective Review Update

The Department of Health and Human Services (HHS) continues to make progress in its retrospective review work, as directed by the President's Executive Orders (EOs) 13563 (*Improving Regulation and Regulatory Review*) and 13610 (*Identifying and Reducing Regulatory Burdens*). To date, HHS has published 37 proposed rules and 33 final rules related to retrospective review, in addition to completing review of rulemakings where regulatory changes have not been deemed necessary. This July 2014 update highlights two major accomplishments since the Department's last update in January.

Updates to Nutrition Facts Label on Food Packages

In March, the Food and Drug Administration proposed to update the Nutrition Facts Label for packaged foods to reflect the latest scientific information, including the link between diet and chronic diseases such as obesity and heart disease. The proposed label would also replace out-of-date serving size information to better align with how much people really eat, and the label would feature a fresh design to highlight its key parts, such as information on calories and serving sizes.

Some of the changes to the label would:

- Require information about the amount of "added sugars" in a food product. The 2010 Dietary Guidelines for Americans states that intake of added sugar is too high in the U.S. population and should be reduced. The FDA proposes to include "added sugars" on the label to help consumers know how much sugar has been added to the product.
- Update serving size requirements to reflect the amounts people currently eat. What and
 how much people eat and drink has changed since the serving sizes were first put in place
 in 1994. By law, serving size information must be based on what people actually eat, not on
 what people "should" be eating. The proposed rule would also require calorie and nutrition
 information for the whole package of certain food products that could be consumed in one
 sitting.
- Present "dual column" labels to indicate both "per serving" and "per package" calorie and nutrition information for larger packages that could be consumed in one sitting or multiple sittings.

Reducing Unnecessary Costs and Increasing Flexibility for Health Care Providers

In May, the Department completed rulemaking responding directly to EO 13563. This is the latest in a series of rules developed over the last 5 years by the Centers for Medicare and Medicaid Services (CMS) to reform existing rules to reduce unnecessary costs and increase flexibility for health care providers. This final rule reduces the burden of outmoded Medicare rules concerning numerous daily practices in hospitals, thereby increasing the ability of health care entities to focus resources on providing high-quality patient care. Additionally, we estimate

that the overall national cost savings created by this rule will be between approximately \$230 million to \$830 million per year annualized over the next 5 years.

Examples of the burden reductions put in place by this rule include:

- Radiology services in ambulatory surgical centers: We are reducing the requirements that Ambulatory Surgical Centers (ASCs) must meet in order to provide radiological services to patients. Our requirements now reflect only those services that ASCs are permitted to perform. ASCs had been subject to the full hospital requirements for radiology services.
- Hospital registered dietitian privileges: We are permitting registered dietitians and other clinically qualified nutrition professionals to be authorized to order patient diets under the hospital conditions of participation (CoPs).
- Hospital reclassification of swing bed services: We are revising the requirements by relocating the swing bed-services CoPs to classify swing beds as an optional service. This revision allows an accredited hospital's compliance with swing bed requirements to be evaluated by a CMS-approved accrediting organization, reducing the burden on hospitals by not requiring an additional state survey specifically for swing bed approval.
- Transplant center reports to CMS: The CoPs require transplant programs to notify CMS of certain changes related to the center's program. The current system for transplant center data analysis requires the centers to submit data which CMS routinely receives through other sources. This creates unnecessary paperwork and does not contribute to federal oversight. We are eliminating this redundant data submission requirement.